

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Offer alternative ways to improve the proposed rule or collection activity.

7. Make sure to submit your comments by the deadline in this document.

8. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. Background and Statutory Findings

EPA, in cooperation with DuPont Crop Protection and university extension specialists, under section 408(e) of the FFDCA, 21 U.S.C. 346a, is proposing to establish a tolerance for combined residues of the insecticide Indoxacarb, in or on peaches at 10.0 parts per million (ppm). This action is in response to university extension specialists, DuPont, and EPA's combined efforts to generate the information necessary for registration of the reduced risk pesticide, Indoxacarb, on peaches for control of oriental fruit moth and plum cuculio. This proposed temporary tolerance supports a non-crop destruct experimental use permit (EUP) under section 5 of FIFRA

authorizing use of Indoxacarb on peaches in Georgia, Michigan, New Jersey, Pennsylvania, South Carolina, and West Virginia. Section 5 of FIFRA authorizes EPA to issue an experimental use permit for a pesticide. This provision was not amended by FQPA. EPA has established regulations governing such experimental use permits in 40 CFR part 172. Section 408(r) of FFDCA authorizes EPA to issue temporary tolerances for pesticide residues from FIFRA experimental use permits.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of the FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue * * *"

EPA performs a number of analyses to determine the risks from aggregate

exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for a tolerance for combined residues of Indoxacarb on peaches at 10.0 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by Indoxacarb are discussed in Table 1 of this unit as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies reviewed.

TABLE 1.— SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90-Day oral toxicity rodents	DPX-MP062 NOAEL = M 3.1 mg/kg/day F 2.1 mg/kg/day LOAEL = M 6.0 mg/kg/day, F 3.8 mg/kg/day based on decreased body weight, body weight gain, food consumption and food efficiency.
870.3150	90-Day oral toxicity in nonrodents	DPX-JW062 NOAEL = 5.0 mg/kg/day LOAEL = 19 mg/kg/day based on hemolytic anemia, as indicated by decrease in HGB, RBCs; increases in platelets, increased reticulocytes; and secondary histopathologic findings indicative of blood breakdown (pigment in Kupffer cells, renal tubular epithelium, and spleen and bone marrow macrophages); increase in splenic EMH; and RBC hyperplasia in bone marrow in dogs.
870.3200	21/28-Day dermal toxicity	DPX-MP062 NOAEL = 2,000 mg/kg/day LOAEL = >2,000 mg/kg/day in rats. DPX-MP062 NOAEL = 50 mg/kg/day LOAEL = 500 mg/kg/day based on decreased body weights, body weight gains, food consumption, and food efficiency in F*, and changes in hematology parameters (increased reticulocytes), the spleen (increased absolute and relative weight M* only, gross discoloration), clinical signs of toxicity in both sexes in rats.